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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,147	09/30/2003	Gilbert R. Gonzales	XANO / 36	5607
26875	7590	06/01/2006	EXAMINER	
WOOD, HERRON & EVANS, LLP 2700 CAREW TOWER 441 VINE STREET CINCINNATI, OH 45202			HUH, BENJAMIN	
			ART UNIT	PAPER NUMBER
			3767	

DATE MAILED: 06/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/675,147	Applicant(s) GONZALES, GILBERT R.	
	Examiner Benjamin Huh	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/1/06.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/2/04 & 12/31/03</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-27 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 5846216 in view of Evans et al (US Pub. No. 2001/0049486A1). The Gonzales reference ('216) recites an infusor system for administering medications in a body of a patient comprising a flexible, elongated delivery tube. Now, even though Gonzales does not explicitly recite a delivery component and a pressure altering device or the use with venous blood vessels attention is directed to Gonzales & Evans, the Gonzales('216) recites a dispenser head which is an equivalent structure to that of the delivery component and also teaches the

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use of a pressure altering device, see col. 2 line 43 – col. 3 line 14 & col. 6 lines 15-27 and Evans teaches delivering medications to a venous blood vessel. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to utilize the teachings of Gonzales and Evans in order to utilize a pressure-altering device and administer to the venous blood vessels in order to aid in medication delivery to a desired location.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 23, & 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gonzales et al (US Patent No. 5846216) and further in view of Evans et al (US Pub. No. 2001/0049486A1). The Gonzales reference discloses an infusor system for administering medications in a body of a patient comprising a flexible, elongated delivery tube having opposite ends, one of said ends couplable to a supply of liquid medication, said supply being remote from a venous blood vessel; a delivery component, and a pressure altering device, see col. 2 line 43 – col. 3 line 14 & col. 6 lines 15-27. Wherein the delivery component would be fully capable of being placed in confronting relationship with the venous blood vessel so that medication from said supply may be introduced directly into the venous blood vessel and distributed in the body of the patient due to it's size, shape, and ability to work in the environment. Now, even though Gonzales does not disclose the administration of medication through

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venous means attention is directed to Evans. The Evans et al reference discloses administration of medication through venous means. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention ^{was made} to ^{modify the teachings of} utilize the teachings of Gonzales by ^{ing} Evans in order to administer the medication to the desired location.

Claims 2-3 & 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gonzales et al (US Patent No. 5846216) in view of Winchell et al (US Patent No. 5601243). Even though Gonzales does not disclose the delivery component with the venous needle and the medications attention is directed to Winchell. The Winchell reference teaches the use of a venous needle delivering medications, see claim 5, col. 3 lines 3-13, col.5 lines 55-58, and col. 10 line 67- col. 11 line 7. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Gonzales with the teachings of Winchell in order to provide a means of entering the blood vessel and to improve function.

Claims 5-7 & 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al (US Pub. No. 2001/0049486) in view of Gonzales (US Patent No. 5846216). Evans discloses the administration of medication through a venous means to an injection site. Now even though Evans does not explicitly disclose the use of liquid medication or a valve allowing flow attention is directed to Gonzales. The Gonzales reference teaches a liquid medication and a valve allowing flow, see claims 5 & 6 and col. 4 lines 12-19. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the device of Evans with the teachings of Gonzales in order to administer liquid medication and control the flow.

Claims 9-12 & 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al (US Pub. No. 2001/0049486a1) in view of Gonzales (US Patent No. 5846216). Now even though Evans does not explicitly disclose an increase abdominal pressure attention is directed to Gonzales. The Gonzales reference teaches an increase in intra-abdominal pressure utilizing a binder or restraint, see col. 2 line 43 – col. 3 line 14 & col. 6 lines 15-27. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the device of Evans with the teachings of Gonzales in order to control the intra-abdominal pressure to help deliver medication. Wherein, it would be obvious to one of ordinary skill in the art to increase the pressure to a level necessary for reversing blood flow to administer the medications, wherein the level would have to be high enough to reverse blood flow, which could be greater than 30 mm Hg.

Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gonzales et al (US Patent No. 5846216) in view of Gordon et al (US Pub No. 2002/0188253a1). Now even though Gonzales does not explicitly disclose a method of administering medication including the initiation of flow of medication and the injection site from the syringe to the tube attention is directed to Gordon. The Gordon reference teaches a method of administering medication, including the initiation of flow of medication and the injection site from the syringe to the tube, see claims 16-17 & 20. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to administer the medication in such a manner as to improve delivery of the medication.

Claims 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al (US Pub. No. 2001/0049486a1) in view of Gonzales (US Patent No. 5846216). Even though Evans does not explicitly disclose an IV bag with a connecting pump attention is directed to Gonzales. The Gonzales reference teaches the use of an IV bag with a connecting pump, see col. 4 lines 12-19. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to utilize the teachings of Gonzales in the device of Evans in order to administer a medication from an IV bag at a faster rate.

Claims 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al (US Pub. No. 2001/0049486a1) in view of Gonzales (US Patent No. 5846216). Even though Evans does not explicitly disclose the spinal region of the body where the liquid medication is delivered attention is directed to Gonzales. The Gonzales reference teaches delivering liquid medication to a spinal region of the body, see col. 12 line 28 – col. 13 line 28. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to utilize the teachings of Gonzales in the device of Evans in order to deliver the medication to the desired location for proper treatment.

Response to Arguments

Applicant's arguments filed 3/1/06 have been fully considered but they are not persuasive.

Applicant argues that the Gonzales reference is not applicable since it discloses that there are problems with IV treatment and therefore would have no motivation to utilize IV treatment. Examiner respectfully disagrees. Examiner notes that the claims for the infusor system state for administering medications to a venous blood vessel are an intended use and wherein it can be "adaptable for being placed in a venous blood vessel". Since, the device of Gonzales and Evans would be fully capable of performing the functional language of the device of the instant application due to it's size, shape, and ability to work in the environment it reads on the current claims. Also, even though the reference notes problems with IV treatment it does not explicitly state not to utilize IV treatment and therefore the Evans and Gonzales references can still be motivated to utilize IV treatment when used together.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Huh whose telephone number is 571-272-8208. The examiner can normally be reached on M-F: 9:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BHH

BHH

KEVIN SIRMONS
PRIMARY EXAMINER

Kevin C. Sirmons